REMARKS

Claims 1-4 have been amended to more definitely set forth the invention and obviate the rejections. Specifically, claims 1 and 2 have been amended to call for the oral administration of sphingomyelin as an effective ingredient, as well as the specific weight percent of sphingomyelin provided in the composition. Support for the amendment of claims 1 and 2 can be found in the specification on page 5, lines 9-15. In addition, new claims 8 and 9 have been presented herein. Support for the subject matter of new claims 8 and 9 can be found in the Specification on page 7, first paragraph, and on page 9, in Table 1. The present amendment is deemed not to introduce new matter. Claims 1-9 are now in the application, claims 5-7 having been previously withdrawn from consideration.

Although the Examiner has not clearly predicated a rejection of any specific claims based on the previously cited Msika, et al., Nieuwenhuizen, et al. or Greff, et al. references, the Examiner's comments in the "Response to Arguments" section, bridging pages 2-5 of the instant final Office Action, are duly noted. In response thereto, the undersigned respectfully comments as follows:

As the Examiner has recognized, Msika, et al. is concerned with the prevention of allergic dermatitis. However, there is no disclosure whatever in Msika, et al. of increasing the moisture content or decreasing transepidermal water loss of the skin via the oral administration of a composition containing *0.000001 to 0.004 wt%* of sphingomyelin. On the contrary, that teaching

or suggestion, as now clearly called for in the amended claims herein, comes only from the present application.

The undersigned maintains that the Examiner's secondary reference of Nieuwenhuizen fails to cure the deficiencies of the primary reference of Msika, et al. Rather, Nieuwenhuizen discloses a method for improving the composition of intestinal flora. Although this method does involve the consumption of pharmaceuticals and foods containing sphinolipids, there is no disclosure in Nieuwenhuizen that food containing sphingomyelin decreases transepidermal water loss of the skin and thus results in beautifying effects thereto. Further, Nieuwenhuizen discloses pharmaceuticals and foods having weight percents of sphingolipids far greater than called for in the compositions of the present invention (see Nieuwenhuizen, paragraphs [0047] and [0069], which call for 0.05 to 50 wt% and 0.01 to 99.9 wt%, respectively).

Lastly, the Greff, et al. reference discloses a topically applied cream, not an orally administered composition as called for herein. Moreover, Greff clearly calls 0.01 to 30% weight percent of sphingomyelin in the disclosed cream (see page 6, second paragraph). In contrast, the present invention, as now called for herein in amended base claim 1, calls for 0.000001 to 0.004 wt% of sphingomyelin in an orally administered composition. Thus, Greff, et al. clearly fail to teach or suggest the presently claimed composition, nor the unexpected effects achieved thereby.

With regards to the Examiner's comments concerning the skin-beautifying effects of the present invention, as called for in the preambles of claims 3 and 4, it is urged that increasing moisture content of skin naturally leads to more beautiful, healthy skin. Thus, this effect is clearly tied to the unexpected effects illustrated by the comparative tests disclosed in the

specification, and as described in detail below.

In view of the above, it is respectfully submitted that, if the Examiner intended to maintain a rejection on the above-cited prior art references, the examiner's combination of references taken either individually or in combination fail to teach or suggest the subject matter now called for in the claims as amended herein. Accordingly, withdrawal of any intended rejection based on the above mentioned prior art is respectfully requested.

Reconsideration is respectfully requested of the rejection of Claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Yukihiro, et al. (JP 2001-158736).

Yukihiro, et al. teach a prevention and improvement agent for bone and joint disease. The composition of Yukihiro, et al. contains sphingosine skeletons contained in cow's milk or bovine brain, such as ceramide, sphingomyelin, sphingoglycolipid and ganglioside. Yukihiro, et al. teach that these components are blended with food or drink to prevent and treat bone and joint diseases such as osteoporosis.

In contrast, the present invention provides an orally administered skin moisturizer and skin beautifier, as well as a skin-beautifying food or feed, comprising 0.00001-0.004 wt% of sphingomyelin as an effective ingredient in moisturizing and beautifying the skin. Yukihiro, et al. fail to teach or suggest an orally administered skin moisturizer and skin beautifier, or a skin-beautifying food or feed, comprising 0.00001-0.004 wt%. Rather, this teaching or suggestion comes only from the present invention, as now claimed herein, and constitutes an important element or aspect thereof. Further, Yukihiro, et al. fail to recognize in any way the applicability of sphingomyelin to the treatment of skin, which is the focus herein.

Objective evidence of secondary considerations, such as unexpected results, are relevant to the issue of obviousness and must be considered in every case in which they are present. See MPEP 2141 II. It is the duty of the Examiner to evaluate such evidence. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed.Cir., 1983); and *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed.Cir., 1986), cert. denied, 480 U.S. 947 (1987).

Proof of an unexpected improvement can rebut a prima facie case of obviousness. *In re Murch*, 464 F.2d 1051, 175 USPQ 89 (CCPA, 1972). No matter how strong the prima facie case of obviousness made out by the PTO, it must be weighed against any factors to the contrary brought out by the applicant in determining the validity of the conclusion of patentability unobviousness. *In re Lewis*, 443 F.2d 489, 170 USPQ 84 (CCPA, 1971). Therefore, facts established by rebuttal evidence must be evaluated along with the facts on which the conclusion was reached, not against the conclusion itself. *In re Lilly & Co.*, 902 F. 2d 943, 14 USPQ 2d, 1741 (CAFC, 1990).

With regards to unexpected improvements, as described in the instant Specification, on page 9 through the first paragraph on page 11, the present inventors conducted comparative tests on animals (mice) to determine the effectiveness of the presently claimed orally administered skin moisturizer and skin beautifier comprising sphingomyelin. In particular, mice were divided into 4 separate groups as follows:

Group A: receiving 10 g of physiological saline per kg of mouse body weight;

Group B: receiving 10 g of the Test Feed 1 per kg of mouse body weight;

Group C: receiving 10 g of the Test Feed 2 per kg of mouse body weight; and

Group D receiving 10 g of the Test Feed 3 per kg of mouse body weight.

Moisture contents and transepidermal water losses in the tail skin of each mouse were measured at the beginning of the testing. Then, the feed of the present invention was orally administered to each mouse in each of the 4 Groups for 4 weeks. At the end of the 4 weeks, the moisture contents and transepidermal water losses in the tail skin of each mouse were measured. The results of these measurements are shown in Table 2 on page 10 of the Specification.

Specifically, it was unexpectedly discovered that in Group A, i.e., the mice that received no sphingomyelin, the moisture content of the skin after the 4-week test period remained virtually unchanged. However, the moisture content of the skin in the mice of Group B increased by about 1.5 times, and by about 2.5 times in the mice in Groups C and D. Further, it was unexpectedly discovered that the transepidermal water loss after the 4-week administration period increased by about 1.7 times in Group A, but increased only by about 1.5 times in Group B and by about 1.4 times in Groups C and D. Thus, it is respectfully submitted that the comparative test results illustrated unexpected improved results, i.e., that the oral administration of the skin moisturizer and skin beautifier composition of the present invention significantly increases the moisture content of the skin over time, and greatly decreases the transepidermal water loss of the skin over time. These unexpected improvements were observed by administering 2 mg or more of sphingomyelin per kg of mouse body weight, and were further increased by administering 5 mg or more of sphingomyelin per kg of mouse body weight.

In view of the amendments made herein, the comparative tests discussed above, and the

above cited legal authorities, it is believed that the Examiner would be justified in no longer maintaining the rejection. Withdrawal of the rejection is accordingly respectfully requested.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action and allowance thereof is accordingly respectfully requested. In the event there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems.

Respectfully submitted,

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